

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA *EX REL.*
BRUCE BOISE, KEITH DUFOUR AND
ANDREW AUGUSTINE AND ON BEHALF OF
THE STATES OF CALIFORNIA,
CONNECTICUT, DELAWARE, FLORIDA,
GEORGIA, HAWAII, ILLINOIS, INDIANA,
LOUISIANA, THE COMMONWEALTH OF
MASSACHUSETTS, MICHIGAN, MONTANA,
NEVADA, NEW JERSEY, NEW YORK,
NORTH CAROLINA, OKLAHOMA, RHODE
ISLAND, TENNESSEE, TEXAS, THE
COMMONWEALTH OF VIRGINIA,
WISCONSIN AND THE DISTRICT OF
COLUMBIA,

PLAINTIFFS,

V.

CEPHALON, INC., A WHOLLY-OWNED,
DIRECT SUBSIDIARY OF TEVA LIMITED,
AND JOHN DOES # 1-100, FICTITIOUS
NAMES,

DEFENDANTS.

Hon. Thomas N. O'Neill, Jr.

Civil Action No. 08-287

ORAL ARGUMENT REQUESTED

**CEPHALON'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO
MODIFY THE COURT'S JULY 30, 2015 ORDER, OR, IN THE ALTERNATIVE,
MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS**

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I. INTRODUCTION

Cephalon respectfully moves this Court to modify its July 30, 2015 Order (Doc. No. 137) to dismiss Relators' Provigil claims without prejudice to file a separate civil action unimpeded by the False Claims Act's ("FCA") first-to-file jurisdictional bar. While Cephalon agrees with the Court that, based on the Supreme Court's recent decision in *Kellogg Brown & Root Services, Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970 (2015) ("*Carter*"), a previously dismissed case does not entirely preclude Relators' Provigil claims under the first-to-file rule, (Doc. No. 137 at 1), Cephalon respectfully submits that it is a clear error to allow Relators' claims to proceed without first curing the jurisdictional defect caused by the first-to-file rule.

As the Court correctly noted in its July 30 Order, the *Carter* holding permits Relators' Provigil claims to proceed in the face of an earlier-filed, but dismissed, related action based on the same underlying facts. But the Supreme Court did not go so far as to hold that such claims may proceed without first curing the underlying jurisdictional defect. Indeed, the decision held only that dismissal *with prejudice* was improper. Here, Relators initiated their Provigil claims with their First Amended Complaint ("FAC"), which was filed at a time when an earlier-filed related action, *United States ex rel. Doe v. Cephalon*, No. 09-2926 (E.D. Pa.) (the "*Doe* Action"), was pending and, therefore, the claims suffered from a jurisdictional defect. Accordingly, any pleading subsequent to the FAC (including the Second Amended Complaint ("SAC") and Third Amended Complaint ("TAC")) is infected by the same jurisdictional defect, which cannot be cured. Thus, in light of *Carter*, while Relators may assert claims concerning Provigil, the proper procedural course is to dismiss Relators' Provigil claims without prejudice to file a separate civil action, now that the *Doe* Action has been dismissed.

In the alternative, Cephalon moves this Court for partial judgment on the pleadings to dismiss Relators' Provigil claims that arose before February 28, 2008, which is six years prior to

when the SAC was filed. Partial judgment on the pleadings is warranted because an amended pleading cannot relate back to the time of filing of a complaint over which the court did not have jurisdiction. Here, the Court lacked subject-matter jurisdiction over the Provigil claims when the FAC was filed, because the *Doe* Action was pending at that time. Accordingly, should the Court deny Cephalon's motion to modify, which could cure any jurisdictional defects, then the SAC is the first Provigil filing over which the Court could have possibly had jurisdiction, and the statute of limitations must be determined from February 28, 2014, when the SAC was filed.

II. PROCEDURAL HISTORY

Relator Boise filed an original complaint on January 3, 2008, alleging off-label promotion of Fentora. Doc. No. 1 ¶ 2. Boise then amended his complaint on January 14, 2010, which is the first time he brought claims for Provigil. Doc. No. 14 ¶ 2. With Cephalon's motion to dismiss the FAC pending, Boise, now joined by new relators Augustine and Dufour, filed a SAC on February 28, 2014. Doc. No. 69. Finally, Relators amended their complaint for a third time on May 1, 2015. Doc. No. 121.

The FAC, SAC and TAC all allege off-label promotion of Provigil. *See* FAC ¶¶ 2, 98-99; SAC ¶¶ 3, 89-91; TAC ¶¶ 3, 89-91. Before the FAC, SAC or TAC was filed, however, a case making substantially the same allegations regarding an alleged scheme to market Provigil off-label was already pending in this district. That case, brought by unidentified relators, was filed on June 30, 2009 ("*Doe* Complaint").¹ The *Doe* Action was eventually dismissed on September 19, 2013, only after Relators filed the FAC in this case.

¹ The *Doe* Complaint is attached to Cephalon's Motion to Dismiss on First-to-File Grounds as Exhibit A. *See* Doc. No. 78-2 (not filed electronically pursuant to L.R. 5.1.2(6)).

Set forth below is a summary of the relevant pleadings, the dates that they were filed, and the products at issue in each action:²

Date Filed	Case/ Relators	Relevant Pleading/Filing	Products At Issue
Jan. 3, 2008	<i>Boise</i>	Original Complaint filed. Doc. No. 1.	Fentora
June 30, 2009	<i>Doe et al</i>	Original Complaint filed.	Fentora & Provigil
Jan. 14, 2010	<i>Boise</i>	First Amended Complaint filed. Doc. No. 14.	Fentora, Provigil & Nuvigil
Sept. 12, 2013	<i>Boise</i>	Boise FAC is unsealed. Doc. No. 37.	Fentora, Provigil & Nuvigil
Sept. 19, 2013	<i>Doe et al</i>	<i>Doe</i> Action Dismissed.	Fentora, Provigil & Nuvigil
Feb. 28, 2014	<i>Boise Augustine Dufour</i>	Second Amended Complaint is filed. Doc. No. 69.	Fentora, Provigil & Nuvigil
May 1, 2015	<i>Boise Augustine Dufour</i>	Third Amended Complaint is filed. Doc. No. 121.	Fentora, Provigil & Nuvigil

On April 4, 2014, Cephalon filed a Motion to Dismiss the SAC on First-To-File Grounds. Doc. No. 78. The motion was based, in part, on the fact that Relators' FAC was filed while the Doe Action was pending. *See* Doc. No. 78-1 at 6-9. After briefing was completed (*see* Doc. Nos. 89 & 91), on October 9, 2014, the Court stayed its decision pending resolution of the Supreme Court's decision in *Carter*. *See* Doc. No. 95. On June 2, 2015, Relators submitted a Notice of Supplemental Authority, notifying the Court that the Supreme Court issued its opinion in *Carter* and held that "dismissal with prejudice of the plaintiff-relator's claim based on an

² The summary chart does not reflect all of the pleadings filed in the *Doe* Action, in which the Doe Relators added claims regarding Nuvigil.

earlier filed – but dismissed – related case, was error.” Doc. No. 124. On July 30, 2015, the Court denied Cephalon’s Motion to Dismiss Relators’ Provigil claims on first-to-file grounds. Doc. No. 137.

III. ARGUMENT

A. The July 30, 2015 Order Should Be Modified to Dismiss Relators’ Provigil Claims Without Prejudice to File a New Civil Action.

Cephalon respectfully submits that modification is necessary because it would be a clear legal error to allow Relators’ claims to proceed without first curing the jurisdictional defect caused by the first-to-file rule. Specifically, Relators’ Provigil action was commenced at a time when an earlier-filed related action was pending. This fact not only bars the FAC, but also precludes subject-matter jurisdiction over any subsequent pleading because jurisdiction is analyzed from the time an action is commenced, i.e. the time when the FAC was filed. Accordingly, the only way Relators may proceed with their Provigil case is by filing a new civil action. Critically, following the substantive and procedural dictates of the first-to-file rule is required so that the FCA’s statute of limitations can be appropriately applied.

1. The FAC Is Jurisdictionally Barred by the FCA’s First-to-File Rule.

The FAC is jurisdictionally barred by the first-to-file rule because the *Doe* Action was still pending at the time the FAC was filed. As the Court did not specifically address this argument in its July 30, 2015 Order, Cephalon briefly provides its reasoning and incorporates its arguments from its earlier briefing. *See* Doc. No. 78-1 at 4-9; Doc. No. 91 at 1-4.

Section 3730(b)(5) of the False Claims Act provides that, “[w]hen a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” 31 U.S.C. § 3730(b)(5). This first-to-file rule is an exception-free jurisdictional bar. *See, e.g., United States ex rel. LaCorte v.*

SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 232 (3d Cir. 1998); *United States ex rel. Galmines v. Novartis Pharm. Corp.*, No. 06-3213, 2013 WL 2649704, at *10 (E.D. Pa. June 13, 2013) (finding “the Court lacks subject-matter jurisdiction” over certain claims pursuant to the first-to-file bar); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 16 (1st Cir. 2009) (“[T]he FCA includes jurisdictional bars that limit a district court’s subject matter jurisdiction over qui tam actions.”); *see also* Doc. No. 85 at 1 n.1 (holding that “[e]ach consolidated case must support an independent basis for subject matter jurisdiction” and that the threshold first-to-file jurisdictional issues should be addressed prior to Relators’ motion to consolidate); Doc. No. 91 at 1-2.

In determining whether a relator has met the burden of establishing jurisdiction under Section 3730(b)(5), the key inquiry is whether the later-filing relator brings claims “based on the facts underlying” the original suit. In making this determination, courts apply a material facts standard. *LaCorte*, 149 F.3d at 232. Thus, a “later case need not rest on precisely the same facts as a previous claim to run afoul of this statutory bar. Rather, if a later allegation states all the essential facts of a previously-filed claim, the two are related and section 3730(b)(5) bars the later claim, even if that claim incorporates somewhat different details.” *Id.* at 232-33; Doc. No. 78-1 at 4-5.

There is no dispute that the FAC was filed on January 14, 2010 at a time when the *Doe* Complaint was still pending. Further, as described in detail in Cephalon’s Memorandum of Law, the overlap in material facts between the *Doe* Complaint and the FAC is undeniable. *See* Doc. No. 78-1 at 6-8. Indeed, both complaints allege the same essential off-label promotion scheme of Provigil. *Compare* FAC ¶¶ 2, 98-99 *with* Doe Compl. ¶¶ 57-71. And, both complaints rely on the same supporting allegations:

- Both complaints allege that Cephalon developed an off-label marketing scheme to promote the drug for a variety of off-label indications including chronic fatigue, fatigue associated with depression, fatigue associated with multiple sclerosis and attention deficit disorder. *Compare* FAC ¶ 41 *with* Doe Compl. ¶¶ 3, 63.
- Both complaints allege that Cephalon targeted physicians, including psychiatrists, who wrote prescriptions for off-label uses. *Compare* FAC ¶ 42, 98-99 *with* Doe Compl. ¶¶ 63, 67, 70.
- Both complaints allege that Cephalon utilized paid speakers to facilitate alleged “kickbacks” and promote Provigil off-label. *Compare* FAC ¶ 48, 98-99 *with* Doe Compl. ¶¶ 68-69.
- Both complaints allege that Cephalon expected its sales force to promote off-label because individual compensation levels depended on off-label sales. *Compare* FAC ¶ 43 *with* Doe Compl. ¶¶ 66.
- And, both complaints allege that Cephalon instructed physicians’ office administrators on – or in some cases facilitated for them – obtaining reimbursement for off-label prescriptions of Provigil. *Compare* FAC ¶ 58 *with* Doe Compl. ¶¶ 71.

Thus, the FAC and the *Doe* Complaint contain the same essential facts and, under the first-to-file rule, the Court did not – and under *Carter* still does not – have subject-matter jurisdiction over Relators’ Provigil claims in the FAC.

2. The Jurisdictional Defect Cannot Be Cured Through an Amended Pleading.

Following *Carter*, the proper procedural course is to dismiss Relators’ claims without prejudice, so that Relators may file a separate civil action for its Provigil claims. This is the only way to cure the jurisdictional defect that attaches to the FAC and any subsequent amendment.

The FAC’s jurisdictional defect – that it lacks subject-matter jurisdiction because it was filed before the *Doe* Action was dismissed – attaches to and cannot be cured by any subsequent amendment. *See United States ex rel. Branch Consultants, LLC v. Allstate Ins. Co.*, 782 F. Supp. 2d 248, 267 (E.D. La. 2011) (“[Relator] cannot argue that the dismissal [of the earlier filed action] frees it to rename [Defendant] by amendment because the Court cannot have jurisdiction

over an amended complaint if it did not have jurisdiction when the original complaint was filed.”). Jurisdiction is analyzed from the time Relators commenced their Provigil claims, and not from the time any subsequent amended pleading was filed.³ *See* Doc. No. 91 at 3-4; *see also United States ex rel. Piacentile v. Sanofi Synthelabo, Inc.*, No. 05-2927 (KSH), 2010 WL 5466043, at *4 (D.N.J. Dec. 30, 2010) (“[A] court must ‘judge whether § 3730(b)(5) barred [a] *qui tam* action by looking at the facts as they existed at the time that action was brought.’”) (alteration in original) (citation omitted); *United States ex rel. Carter v. Halliburton Co.*, 710 F.3d 171, 183 (4th Cir. 2013) (“Because we look at the facts as they existed when the claim was brought to determine whether an action is barred by the first-to-file bar, we conclude that [Relator]’s claims are barred by the [earlier-filed] actions”), *aff’d in relevant part, rev’d in part and remanded sub nom. Carter*, 135 S. Ct. 1970 (2015).

In the case underlying the Supreme Court’s decision in *Carter*, the Fourth Circuit held that the first-to-file rule barred Relator’s claims because they were brought at a time when two earlier-filed actions were still pending, even though those actions were later dismissed. *Carter*, 710 F.3d at 183. The only question was whether Relator’s claims should have been dismissed with or without prejudice. *See id.* The Fourth Circuit answered this question by holding that Relator was not prevented from filing a new action now that the earlier-filed litigations were dismissed. *Id.* Adopting reasoning from the Seventh Circuit, the court noted that, “once the initial complaint was no longer pending, the bar of § 3730(b)(5) was inapplicable and [Relator] was ‘entitled to file a new *qui tam* complaint.’” *Id.* (quoting *United States ex rel. Chovanec v. Apria Healthcare Grp., Inc.*, 606 F.3d 361, 365 (7th Cir. 2010)). Thus, dismissal without prejudice was warranted. *See id.*

³ At the time of the motion to dismiss briefing, Relators had not yet filed their TAC. However, the TAC suffers from the same defect as the SAC, as the underlying Provigil claims were brought when the *Doe* Action was pending.

This is the same limit of relief allowed for and addressed by the Supreme Court. *See Carter*, 135 S. Ct. at 1978 (“We . . . consider whether respondent’s claims must be dismissed *with prejudice* under the first-to-file rule. We conclude that dismissal *with prejudice* was not called for.”) (emphasis added). Indeed, Relators acknowledge that the *Carter* decision is limited to a holding that “*dismissal with prejudice* of the plaintiff-relator’s claim based on an earlier filed – but dismissed – related case was error.” *See* Doc. No. 124 at 2 (emphasis added).

The issue here is the same as *Carter*. Relators’ Provigil Action was filed at a time when an earlier filed action, alleging the same essential facts, was pending. *See supra* III.A.1. Thus, the Court lacked subject-matter jurisdiction over Relators’ Provigil Action at the time it was filed and such a defect can only be cured by filing a new civil action. *See Carter*, 710 F.3d at 183; *Branch*, 782 F. Supp. 2d at 267. As was the case in the Fourth Circuit, the only question for this Court is whether Relators’ Provigil claims should be dismissed with or without prejudice to file a new action. *Carter* held that dismissal with prejudice was improper; thus, the proper – and only – procedural course to cure the jurisdictional defect here is to dismiss Relators’ Provigil claims without prejudice to file a new civil action.

3. The Court’s Determination of its Subject-Matter Jurisdiction Bears Directly on the Applicable Statute of Limitations.

Whether Relators are permitted to proceed without curing the jurisdictional defect, or instead must file a separate civil action, is not an academic exercise in federal procedure. To the contrary, the distinction bears directly on the proper application of the statute of limitations. If Relators must file a new action, then the statute of limitations would begin to run from the date the new action is filed because “a complaint filed in one civil action [cannot] relate back to a complaint filed in a separate civil action.” *See, e.g., United States ex rel. Malloy v. Telephonics*

Corp., 68 F. App'x 270, 273 (3d Cir. 2003) (citation omitted). Thus, following the required procedural course directly impacts more than a year's worth of Relators' Provigil claims.

In similar procedural settings, courts have held that, where an original complaint is jurisdictionally defective, the proper course is to file a new action. *See Morgan v. Hanna Holdings, Inc.*, 635 F. Supp. 2d 404, 411 (W.D. Pa. 2009) (holding subject-matter jurisdiction could not be conferred after statute of limitations had run on copyright infringement claims by amending complaint to reflect events that occurred subsequent to commencement of action); *cf. Brewer-Giorgio v. Producers Video, Inc.*, 216 F.3d 1281, 1285 (11th Cir. 2000) (finding it proper to disallow amendment where registration of copyright, which was necessary to confer subject-matter jurisdiction, was not effected until after statute of limitations expired), *abrogated on other grounds by Reed Elsevier, Inc. v. Muchnick*, 559 U.S. 154 (2010); *Wellness Publ'g v. Barefoot*, No. 02-3773 (JAP), 2008 WL 108889, at *10-11 (D.N.J. Jan. 9, 2008) (dismissing copyright claims because amended complaint was barred by statute of limitations and could not relate back because subject-matter jurisdiction did not exist "at the outset of the action").

For example, in *Morgan*, the court did not have subject-matter jurisdiction over plaintiffs' copyright claims at the time the original complaint was filed because the work in question was not registered, a jurisdictional prerequisite. 635 F. Supp. 2d at 409. While recognizing that courts generally permit a jurisdictional defect to be cured through an amended pleading, the court made clear that such a procedural shortcut is not appropriate where "the statute of limitations on Plaintiffs' infringement claims had run prior to Plaintiffs seeking leave to correct the deficiency in their pleading." *Id.* at 410. Thus, "the proper course for a plaintiff who has filed a jurisdictionally deficient copyright infringement claim, upon satisfying the jurisdictional prerequisite of registration, is to file a new action." *Id.*

Like the registration defect in *Morgan* which prevented subject-matter jurisdiction over Plaintiff's copyright claims until a time that the work could be registered, here the first-to-file bar prevents the Court from exercising subject-matter jurisdiction because the action was initially brought at a time when the earlier-filed *Doe* Action was pending. The only way to fix this jurisdictional defect is for Relators to file a new civil action for their Provigil claims.

Accordingly, Cephalon respectfully submits that modification of the Court's Order is warranted, consistent with *Carter*, to dismiss Relators' Provigil claims without prejudice to file a separate civil action.

B. In the Alternative, Judgment Should be Granted in Cephalon's Favor on Relators' Provigil Claims Prior to February 28, 2008, Because They Are Barred by the FCA's Six-Year Statute of Limitations.

If the Court does not modify its July 30, 2015 Order to dismiss Relators' Provigil claims without prejudice, then partial judgment on the pleadings is appropriate to dismiss Relators' Provigil claims prior to February 28, 2008 (which is six years prior to the date the SAC was filed). Dismissal of Relators' pre-February 28, 2008 claims is required because an amended pleading cannot relate back to an earlier jurisdictionally deficient pleading and, therefore, Relators' Provigil claims must be judged from the date the SAC was filed, February 28, 2014.

"A defendant may raise the statute of limitations as a defense by way of a motion for judgment on the pleadings under Rule 12(c), if the statute's application is apparent on the face of the complaint." *Tozer v. Darby PA*, No. 13-2005, 2014 WL 1378817, at *3 (E.D. Pa. Apr. 7, 2014). Here, the statute's application is apparent on the face of the TAC.

The FAC is jurisdictionally barred by the first-to-file rule because it was brought at the same time that the earlier-filed *Doe* Action was pending. *See supra* III.A.1. Because an amended pleading "cannot relate back to a complaint over which the Court did not have subject matter jurisdiction," Relators' Provigil claims in the SAC and TAC may not relate back to the

FAC. *See Morgan*, 635 F. Supp. 2d at 411 (citing *Kreider Dairy Farms, Inc. v. Glickman*, 190 F.3d 113, 121 (3d Cir. 1999)); *Wellness Publ'g*, 2008 WL 108889, at *10; *Brewer-Giorgio*, 216 F.3d at 1285-86 (“[E]ven if the new claims relate back to the original claims, they may not be added because the district court did not have jurisdiction to hear the new claims at the time the original claims were filed.”) (citing *Reynolds v. United States*, 748 F.2d 291, 293 (5th Cir. 1984)).

Thus, if the Court does not dismiss Relators’ Provigil claims without prejudice to file a new action, then, at a minimum, Relators’ Provigil claims must be judged from February 28, 2014, when the SAC was filed. Since a FCA claim “may not be brought more than 6 years after the date on which the violation of Section 3729 is committed,” 31 U.S.C. § 3731(b)(1), Relators’ Provigil claims prior to February 28, 2008 are barred by the FCA’s six-year statute of limitations and should be dismissed.

IV. **CONCLUSION**

For the foregoing reasons, Cephalon respectfully submits that the Court should modify its July 30, 2015 Order to dismiss Relators’ Provigil claims without prejudice to file a new civil action, or, in the alternative, grant partial judgment on the pleadings to dismiss Relators’ Provigil claims that arose prior to February 28, 2008.

Respectfully submitted,

DATED: August 13, 2015

/s/ Eric W. Sitarchuk

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